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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,024	02/15/2002	G. Ganga Raju	IHEAL-01063US1	5778

23910 7590 10/25/2005

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EXAMINER	
VANIK, DAVID L	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/463,024	RAJU, G. GANGA	
	Examiner	Art Unit	
	David L. Vanik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *1-11,13-16,18-20 and 22-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12,17 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. 8/24/2005
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Arguments filed on 8/22/2005. Receipt is also acknowledged of Applicant's Information Disclosure Statement filed on 8/24/2005.

As a result of Applicant's amendment, the *35 USC §103* rejection over US 3,764,692 in view of WO 98/28989 is hereby **withdrawn**. The *35 USC §103* rejections over US 3,764,692 in view of 5,536,516 and 5,536,516 in view of WO 98/28989 are hereby **maintained** with respect to the instant claims 12 and 17.

Election/Restrictions

Newly amended claims 1-11, 13-16, 18-20, 22-23 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The invention as originally claimed comprises the following: (1) hydroxycitric acid, (2) calcium, and (3) potassium **or** sodium (Claim 1 from the 2/15/2005 amended claims). Additionally, a food product comprising the following was claimed: (1) at least 40% by weight of hydroxycitric acid, (2) 14 to 26% by weight of calcium, and (3) 24-40% by weight of potassium **or** 14-24% by weight of sodium (Claim 12 from the 2/15/2005 amended claims). The office action mailed on 5/23/2005 was searched and examined with respect to the above invention.

The instant claims 1-11, 15-16, 18-20, 22-23 deviate from the scope of the previous invention in that they concern a composition comprising (1) hydroxycitric acid and (2) two or more cations; with the proviso that if one of the cations is magnesium than the other cations are selected from the group consisting of sodium, potassium, calcium, ammonium, and substituted ammonium. Additionally, the instant claims 13-14 deviate from the scope in the elected invention in the sense that they require the presence of the following: 1) hydroxycitric acid, (2) calcium, and (3) potassium **and** (4) sodium.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 1-11, 13-16, 18-20, 22-23 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. JP 10262610

MAINTAINED REJECTIONS

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 3,764,692 ('692) in view of US patent 5,536,516 ('516).

'692 teach weight loss compositions comprising (-) hydroxycitric acid (column 1, lines 21-34 and Claims 1-12). The hydroxycitric acid-based composition (also referred to as garcinia acid) may be utilized as a salt (column 2, lines 1-8). In preferred embodiments, the hydroxycitric acid-based composition may include salts of sodium or potassium and can also include calcium or a complex of said salts (column 2, lines 1-8). According to '692, hydroxycitric acid-based compositions are useful for treating obesity (column 2, lines 26-27 and Claim 1). The hydroxycitric acid-based composition can be administered via capsules, liquids, or tablets and can administered to mammals in a dosage between 1 mg/kg to about 25 mg/kg per day (column 2, lines 35-38 and column 2, lines 46-50). The hydroxycitric acid-based composition can be administered without the lactone form (Claims 1-2; Example 2; Table 3). This is because the lactone form of

hydroxycitric acid is less effective at treating obesity than the sodium salt form of hydroxycitric acid (Examples 1-9 and US patent 6,447,807 B1 column 2, lines 1-6).

'692 does not teach a food product comprising hydroxycitric acid, sodium or potassium, and calcium.

'516 teach snack bars comprising hydroxycitric acid, nutrients, antioxidants, vitamins, or minerals (column 7, lines 1-10). According to '516, the concentration of hydroxycitric acid can be varied depending on the particular type of food product sought (column 7, lines 2-5). Since, as set forth in '692, a composition comprising hydroxycitric acid, sodium or potassium, and calcium, is effective at combating obesity, one skilled in the art would be motivated to incorporate hydroxycitric acid into a food product. The expected result of such a formulation is an effective weight loss food product. Accordingly, one of ordinary skill in the art at the time the invention was made would have been motivated to produce a weight-loss composition comprising a food product, such as a snack bar, and an effective amount of hydroxycitric acid to combat weight loss.

Response to Arguments

Applicant's arguments filed 8/22/2005 have been fully considered but they are not persuasive. Since a food product is a composition, the above rejection is

maintained. It should be noted that Applicant did not specifically point out why the above 103 rejection should be withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,536,516 ('516) in view of in view of WO 98/28989 ('989).

As enumerated above, '516 teach snack bars comprising hydroxycitric acid, nutrients, antioxidants, vitamins, or minerals (column 7, lines 1-10). However, '516 does not teach the same concentrations as set forth in the instant composition.

According to '989, the addition of between 0-30% calcium and 0-30 % potassium to a food product decreases obesity (page 2, lines 17-21). Since, according to '989, the combination of calcium and potassium decreases obesity, one would be motivated to add it to a weight loss composition or formula, such as the one proposed by "516. Based on the teachings of '989 and '516, it is expected that a composition comprising hydroxycitric acid, calcium, and potassium would be an effective weight loss formulation. Accordingly, one of ordinary skill in the art at the time the invention was made would have been motivated to produce a weight-loss composition comprising an effective amount of hydroxycitric acid, calcium, and potassium as suggested by the teachings of '989 and '516.

Response to Arguments

Applicant's arguments filed 8/22/2005 have been fully considered but they are not persuasive. Since a food product is a composition, the above rejection is maintained. It should be noted that Applicant did not specifically point out why the above 103 rejection should be withdrawn.

NEW REJECTIONS

Claim Rejections - 35 USC § 103

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 3,764,692 ('692) in view of US patent 5,536,516 ('516).

The use of a composition to reduce the body weight of an individual is considered to be a future intended use of the composition and, as such, is given no patentable weight.

'692 teach weight loss compositions comprising (-) hydroxycitric acid (column 1, lines 21-34 and Claims 1-12). The hydroxycitric acid-based composition (also referred to as garcinia acid) may be utilized as a salt (column 2, lines 1-8). In preferred embodiments, the hydroxycitric acid-based composition may include salts of sodium or

potassium and can also include calcium or a complex of said salts (column 2, lines 1-8). According to '692, hydroxycitric acid-based compositions are useful for treating obesity (column 2, lines 26-27 and Claim 1). The hydroxycitric acid-based composition can be administered via capsules, liquids, or tablets and can administered to mammals in a dosage between 1 mg/kg to about 25 mg/kg per day (column 2, lines 35-38 and column 2, lines 46-50). The hydroxycitric acid-based composition can be administered without the lactone form (Claims 1-2; Example 2; Table 3). This is because the lactone form of hydroxycitric acid is less effective at treating obesity than the sodium salt form of hydroxycitric acid (Examples 1-9 and US patent 6,447,807 B1 column 2, lines 1-6).

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. JP 10262610 is cited as a patent of interest in its disclosure of a composition comprising calcium, hydroxycitric acid, and a sodium source. Although

pertinent, JP 10262610 appears to have a later priority date (10/6/1998) than the instant application.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik
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